



UNITED STATES PATENT AND TRADEMARK OFFICE

20

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,768	12/30/1999	PINAKI RAY	03764.P002	6849

7590 02/27/2003

DARREN J MILLIKEN
BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP
12400 WILSHIRE BOULEVARD
7TH FLOOR
LOS ANGELES, CA 90025

EXAMINER

SERKE, CATHERINE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,768

Applicant(s)

RAY, PINAKI

Examiner

Catherine Serke

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 14-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13 and 48-60 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 48-51, 53-56 and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Glickman (US Pat#5,817,046).

Glickman discloses a system for fluid isolation in a biological mass having an upstream channel and a downstream channel. The system includes a delivery occlusion conduit (3 or 4) that is positioned adjacent the upstream channel, a collection conduit (9) with at least one balloon that is positioned adjacent the downstream channel (see figure 1). The perfusion fluid is pumped (21) (pressure device/driving force) through the delivery conduit and reclaimed by the collection conduit (see spec 14:25-27). The fluid may be a chemotherapeutic agent. The collection conduit has at least three lumens that are used for fluid collection, a guidewire and balloon inflation.

The device is capable of being used during a substantial period of diastole and/or the period of systole.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3763

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 12-13, 52 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glickman.

Glickman meets the claim limitations as described above but fails to include the occlusion mechanism of the aortic occlusion catheter being an elastomeric balloon and the catheter having three lumens.

At the time of the invention, it would have been obvious to incorporate a balloon as the method of occlusion for the aortic occlusion catheter since balloons are well known in the catheter art to effectively, less-invasively and safely occlude blood vessels. The motivation for making the incorporation would have been in order to provide an occluding device that enhanced the safety to the patient by using a less invasive mechanism.

At the time of the invention, it would have been obvious to incorporate two additional lumens into the aortic occlusion catheter since the reference itself teaches a multi-lumen catheter (i.e. the collection conduit (9)) that has fluid, guidewire and inflation lumens. Having these three lumens in one catheter is common in the art since a balloon catheter if being used to transfer fluids will necessitate at least two lumens (i.e. one for fluid and one to inflate the balloon). Additionally, the procedure of using a guidewire to introduce a catheter into the body is also well known in the art and standard practice to ensure proper and safe placement of the device. The motivation for incorporating an inflation lumen and a guidewire lumen would have been to enable the use of a balloon (see paragraph above) and a guidewire thereby providing a device that has been enhanced for safety of the patient during placement and use.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glickman.

Art Unit: 3763

Glickman meets the claim limitations as described above but fails to include the biological mass being the human heart. At the time of the invention, it would have been obvious to use the invention of Glickman to isolate and perfuse the human heart during procedures such as bypass.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 12/5/02 regarding claims 48-60 have been fully considered but they are not persuasive. First, the examiner makes note that the present claims are device claims and; therefore, the patentability of these claims hinges on structural differences from the prior art. Functional language is given little patentable weight.

In response to applicant's argument that "Glickman does not teach or suggest the desirability of the limitations as recited in independent Claim 48", [emphasis added] the examiner reminds applicant that the "desirability" of an invention is not patentable unless the claims define the instant invention over the prior art. Applicant's argument fails to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., for fluid isolation of only the biological mass and not other tissue structures) are not recited in the rejected

Art Unit: 3763

claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 48 recites “system is adapted for fluid isolation in the biological mass”. The prior art, while achieving fluid isolation by a different method, still achieved fluid isolation in the biological mass and therefore reads on the claims (see 14:5-6).

Furthermore, the above rejection indicates a collection conduit (9) with at least one balloon (see 14:19). The specification column 14 lines 10-25 reads “Tumor 3 located within the thusly isolated circuit is thereafter infused...via catheter 4 and occlusion catheter 3. The thusly infused blood is passed...to the common iliac catheter 9, typically a double balloon catheter...thus isolating substantially all of the outflow blood from the tumor.”

The examiner once again suggests that if applicant wishes to define the instant invention over the prior art by the method and function of the instant invention, then the examiner respectively suggests that applicant pursue method claims. In method claim recitations more patentably weight is given to the function of the device and functional language in the claims.

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3763

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke *CS.*
February 24, 2003

Brian Casler
BRIAN CASLER
SUPERVISOR
TECHNOLOGY CENTER 3763